



FACULTY OF PHARMACEUTICAL MEDICINE

OF THE ROYAL COLLEGES OF PHYSICIANS OF THE UNITED KINGDOM

DIPLOMA IN PHARMACEUTICAL MEDICINE

GUIDANCE FOR CANDIDATES AND SUPERVISORS

EXAMINATION REGULATIONS AND PROCEDURES

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**PART ONE: GUIDANCE NOTES FOR CANDIDATES AND
SUPERVISORS FOR THE DIPLOMA IN
PHARMACEUTICAL MEDICINE**

PREFACE

These notes are intended to provide guidance to physicians studying for the Diploma in Pharmaceutical Medicine (candidates). It is hoped that these notes will clarify the requirements and avoid misunderstandings, thereby enabling candidates to prepare themselves adequately and efficiently. These guidance notes should be read in conjunction with the *Syllabus for Pharmaceutical Medicine*, which is available on the Faculty website and enclosed in the examination pack along with the *Examination Regulations and Procedures* in Part 2.

INTRODUCTION

From 1976, the three UK Royal Colleges of Physicians awarded the Diploma in Pharmaceutical Medicine. In 1994, five years after the creation of the Faculty, responsibility for the Diploma examination was transferred to the Faculty.

The examination is intended to test knowledge and its application relating to all parts of the syllabus, though more weight is given to those areas for which a pharmaceutical physician is likely to be responsible or which have a direct impact on the physician's decision making.

In terms of career progression, passing the examination indicates that the individual has reached a certain level of achievement and has completed a period of training. Possession of the Diploma allows pharmaceutical physicians to apply for Membership of the Faculty of Pharmaceutical Medicine (MFPM). For those pursuing a Certificate of Completion of Training (CCT) or Certificate of Eligibility for Specialist Registration (CESR) in the specialty of Pharmaceutical Medicine in the UK, success in the examination also indicates completion of the required period of basic Pharmaceutical Medicine Specialty Training (PMST).

The examination is held once a year over a period of two days. There are three significant changes to the Diploma examination in 2010.

- As announced in 2009, the assessment of the ability to critique a published paper will be conducted as a written examination, a 'Critical Appraisal Paper', in place of the oral examination held in previous years.
- The examination may be offered at additional examination centres. To accommodate different time zones involved, candidates may be required to remain supervised within the examination centre for the interval between examination papers held on the same day and/or to arrive early or remain after the second paper on each day. An information pack, which

will provide information on timings, will be sent to all candidates after the closing date for entries. Candidates who arrive late will not be permitted to sit the examination.

- An anomaly monitoring system (AMS) may be used to detect instances of copying or collusion by looking for anomalous patterns of responses by candidates, the answers of one candidate being more similar to those of another candidate than would be expected by chance alone.

ELIGIBILITY

The Diploma examination is open to doctors who have entered pharmaceutical medicine and received structured training in the discipline.

Eligibility of candidates to sit the Diploma examination will be assessed at the time of registration for the examination. The criteria are given in the *Examination Regulations and Procedures* in Part 2 of this booklet and are explained below. Where there is doubt, prospective candidates, particularly those from outside the UK, are encouraged to seek advice from the Faculty early in their training rather than at the time of submitting their application to sit the examination.

The Faculty admits only medical graduates to sit the Diploma examination. In this regard, it accepts undergraduate training that leads to the award of a medical qualification recognised by the General Medical Council (GMC) in the UK. All candidates must be registered as medical practitioners.

The Faculty also requires that a candidate has completed full-time training in pharmaceutical medicine for at least two years at the time of sitting the Diploma examination, whether or not the candidate is enrolled in Pharmaceutical Medicine Specialty Training. An equivalent amount of part-time training is accepted provided that the trainee has worked at least 2½ days/week. This experience will almost always be acquired within the pharmaceutical industry, in a contract research organisation or in a drug regulatory authority. Time spent in research within an academic department of a medical school or hospital is rarely appropriate. A senior line manager at the company at which this experience was gained who, ideally, is also a Member or Fellow of the Faculty and/or Educational Supervisor, is required to verify on the application form that the candidate has met this requirement.

Applicants for Membership of the Faculty or for specialty registration are reminded that they must meet additional eligibility requirements. Success in the Diploma examination is necessary but not sufficient.

EDUCATIONAL SUPERVISOR

Candidates who are undertaking Pharmaceutical Medicine Specialty Training (PMST) must have an Educational Supervisor to help them prepare for the Diploma examination. Whilst other candidates for the Diploma examination are not required to have an Educational Supervisor, it is strongly recommended that they do so. Educational Supervisors should meet the

criteria that have been set for Educational Supervisors in Pharmaceutical Medicine Specialty Training. These are available on the Faculty's website.

It is sensible for the Educational Supervisor to be employed in the same organisation and / or the same locality as the candidate. This aids communication, facilitates a one-to-one teacher-pupil relationship, enables the candidate to gain access to personnel and information of relevance to their training and preparation for the examination and helps the candidate obtain the necessary time and resources for their training. If the candidate and their line manager cannot identify an appropriate supervisor within their organisation or locally, the Faculty may be asked to assist in finding a supervisor.

The role of an Educational Supervisor is important. The supervisor should assist in devising the training of a novice pharmaceutical physician, taking into account his or her earlier postgraduate training and past experience. A programme can be outlined to remedy deficiencies in exposure to particular areas of the syllabus. Attendance at training courses, congresses or symposia, provision of CPD teach-in material, distance learning and secondment to other departments of the company or to an external institution may all be considered. The programme should be tailored to the individual's needs and will take into account his or her likely career development. Thereafter, the supervisor should monitor the programme, helping to identify other needs that come to light and how they can be met. The supervisor should also assist the trainee by suggesting reading material, discussing recent developments in pharmaceutical medicine and issues often not covered in textbooks, and providing feedback on practice examination questions.

PREPARATION FOR THE EXAMINATION

A Diploma candidate should plan a training programme in pharmaceutical medicine, where appropriate with the advice of his or her Educational Supervisor. The training in pharmaceutical medicine should involve courses, distance-learning packages, other tuition and personal study.

Candidates are not required to have attended a postgraduate course covering the syllabus for pharmaceutical medicine, though most do. There are many such courses currently being run in Europe including several in the UK. In addition, several courses cover specific areas that fall within the syllabus.

Personal study should supplement other approaches to learning. Study of a current edition of one of the published comprehensive texts such as *The Textbook of Pharmaceutical Medicine*¹ is highly recommended as preparation for the examination. Textbooks on key topics in the syllabus such as clinical trials, pharmacokinetics, medical statistics, safety assessments, etc, are also essential reading. Regulatory guidelines, particularly those issued by ICH, can also be a valuable source of up-to-date information. Regular reading of editorials and articles in the journal *Pharmaceutical Medicine*, *British Journal of Clinical Pharmacology* and general medical journals such as the *New*

¹ The Textbook of Pharmaceutical Medicine. 6th edition Editors Griffin JP, Wiley Publ. 2009

England Journal of Medicine and *The Lancet* provides part of the pharmaceutical physician's lifelong learning and can provide a guide to 'hot topics' that might feature in the examination.

Candidates are advised to study past Short Answer Question and Essay papers, which are available from the Faculty office at a small cost, though, as with all examinations, they should not be taken as an absolute guide to future examinations. It is particularly helpful to practice answering past questions under conditions mimicking the examination and obtain feedback from an Educational Supervisor or compare one's answer with those of colleagues. Past MCQ examination papers are not available to candidates as some questions may be used again.

A valuable exercise by way of preparation for the Critical Appraisal Paper is to undertake critical review of published clinical pharmacology studies, larger clinical trials and epidemiological studies. Making a detailed record of one's views about the Methods and Results before reading the Discussion section makes the process active rather than just accepting the views of the authors. It is particularly useful to critique a paper that forms the subject of an accompanying editorial, again completing the exercise before reading the editorial, which serves as feedback. Comparison of one's responses with those of a colleague can add great value to this exercise.

In addition to reviewing published papers, much can be gained by spending time with colleagues working in different areas of the industry. Like any other medical specialty, pharmaceutical medicine is learned through examples in practice.

The examination tests knowledge and its application relating to *ALL* parts of the syllabus and, in aggregate, a combination of these approaches to preparation must cover all elements of the syllabus. However, some sections are given greater emphasis in the examination and, therefore, require more study. More weight is given to those areas for which a pharmaceutical physician is likely to be responsible such as the management and reporting of serious adverse events occurring during a clinical trial. Knowledge of both principles and practice of therapeutics is considered an essential requirement for pharmaceutical physicians and features prominently in the written examination.

FORMAT OF THE EXAMINATION

The examination is prepared by panels of examiners and the Officers of the Board of Examiners. Core features of the answers and the allocation of marks are also prepared before the examination and distributed for guidance to examiners when the scripts are marked.

There are four papers comprising the written examination.

Day 1

- an MCQ paper of 250 questions (50 stems each with 5 statements) all to be completed in 1 hour 30 minutes;

- a *Short Answer Question* paper of ten questions all to be completed in 2 hours 30 minutes;

Day 2

- an *Essay* paper of four questions of which candidates are required to attempt two in 1 hour 30 minutes
- a *Critical Appraisal* paper in which candidates have 45 minutes to study a published paper followed by 1 hour 15 minutes to answer questions on it.

The time allowed for the written examination is sufficient to complete the papers working at a reasonable pace.

MCQ PAPER

The *MCQ* is intended primarily to test factual knowledge. Each *MCQ* has a stem followed by five statements, any number of which may be true. The candidate is required to identify which are 'true' and which are 'false'. Each correct response earns one mark (maximum of 250 marks overall), no response receives zero marks and an incorrect answer receives zero marks.

SHORT ANSWER QUESTION PAPER

The *Short Answer Question* paper also tests factual knowledge. The questions can bring together several issues and subsections of the syllabus. The candidate is expected to identify the major relevant points and thereby show their understanding of the topic. Candidates should read each question carefully and answer it. Each answer should be written in note or bullet point form.

In total, 10 marks are available for each question (100 marks for the full paper). Candidates should note any guidance provided on the distribution of marks within a question and, if a question consists of more than one part, take care to answer every part.

It is important to attempt every question since 10% of the possible marks will be lost for each question not answered. Candidates who do not attempt or fail to score on three or more questions will fail this paper (and hence the whole examination) whatever their aggregate score is on the remainder of the paper.

ESSAY PAPER

The *Essay* paper also requires knowledge but is designed primarily to test the ability of the candidate to present reasoned argument, expressed in a coherent manner. It is recommended that candidates spend a few moments planning their answer before beginning to write. A substantial proportion of the marks is allotted specifically to demonstration of the ability to analyse a problem, offer solutions and management options and to exercise judgement. Credit is given for good organisation. Some questions may present scenarios and invite a problem-solving answer while others may seek a response showing appreciation of a series of related issues. Answers should *not* be

written in an abbreviated style e.g. listings. The *Essay* paper questions typically bring together several issues and subsections of the syllabus.

CRITICAL APPRAISAL PAPER

The Critical Appraisal Paper is designed to test the ability of candidates to summarise and criticise the important components of work published in a scientific paper of direct relevance to the role of a pharmaceutical physician. Candidates are given 45 minutes to study the set paper, preparing notes if they wish. They then have 1 hour and 15 minutes to answer questions on this paper, referring to the paper and their notes to do so. Each answer should be written in note or bullet point form.

Some questions will test understanding of the paper such as subject selection criteria, study design, analysis and results. Others will focus on discussing the merits of the chosen design and analysis and how it could have been improved, the interpretation and significance of the results for clinical practice, and suggestions for further research. Candidates are not expected to have detailed knowledge of the therapeutic area that was studied.

The question paper will include information on the distribution of available marks, with around one-third being for the test of understanding and around two-thirds allocated to challenging the trial and re-design sections. Candidates should note this information and ensure that they allocate their time appropriately.

GENERAL

It is emphasised that no credit is given in any part of the examination for irrelevant information or discussion of topics outside the scope of the question. Where a question has more than one part, all parts must be answered to gain maximum marks. Marks may be deducted for important errors of commission, particularly if they relate to statements of unsafe and/or unethical actions.

Answers must be legible and the meaning clear; however, poor spelling or grammar are not penalised.

ASSESSMENTS

Standards for the written papers are set using an objective criterion-referenced procedure in which the pass mark and the ranges of marks corresponding to each grade are decided in advance. The procedure takes into account the difficulty of the paper and the standard expected of candidates at Diploma level. There is no limit to the number of candidates who may pass.

The *MCQ* paper is marked by computer.

Each question in the *Short Answer*, *Essay* and *Critical Appraisal* papers is marked independently by at least two examiners using the core features of the answer and guide to allocation of marks provided. Each question is marked

by the same examiners for all candidates to maximise standardisation unless the number of candidates or other factors make this unfeasible. A moderating procedure exists for any individual questions for which a discrepancy arises in the marks awarded. Candidates are identified by their candidate numbers only.

ADJUDICATION

A meeting of the Officers and Panel Convenors of the Board of Examiners is held prior to a full meeting of the Board to award grades for each part of the written examination. The possible grades are: 'Excellent', 'Good', 'Pass', 'Bare Pass', 'Bare Fail' or 'Fail'. It is unusual for a candidate to fail on a single part of the examination but when this does occur the part in question is re-assessed to verify the initial agreed mark or otherwise.

The final decision on 'Pass' or 'Fail' is made at an adjudication meeting of the full Board of Examiners held about six weeks after the examination. Candidates are identified by their candidate numbers only throughout the examination until after the adjudication.

The grades of each candidate in all four parts of the examination are listed. A candidate must obtain at least a 'Bare Pass' in each of the four parts to pass the examination. Candidates given a single 'Bare Fail' will pass the exam if the grades in the other three parts are 'Pass' or higher. Candidates with one 'Bare Fail' and one or more 'Bare Pass' will not pass the examination.

The Board of Examiners may award the Diploma with Distinction to candidates who obtain consistently high grades in the examination.

After completion of the adjudication, a detailed review of the overall results and of the examination procedures is conducted.

Re-marking of written examination papers after completion of the moderation and adjudication processes will only be undertaken at the request of the Appeals Panel in response to a well-founded appeal.

PART TWO: EXAMINATION REGULATIONS AND PROCEDURES

DIPLOMA EXAMINATION

- A.1 The Diploma in Pharmaceutical Medicine (DipPharmMed) is awarded by the Faculty on the recommendation of the Board of Examiners.
- A.2 A Diploma Examination is conducted annually by the Board of Examiners at fixed times and places announced by the Faculty.
- A.3 The Diploma candidate is required to sit a written examination.
- A.4 Membership of the Faculty may be granted to pharmaceutical physicians who possess the Diploma, meet other eligibility criteria, and have their application approved by the Board of the Faculty (see A.37).
- A.5 The Faculty will provide a Diploma Examination pack containing all necessary forms with *Guidance Notes for Candidates and Supervisors*, *Syllabus for Pharmaceutical Medicine* and the *Examination Regulations and Procedures*.

ELIGIBILITY OF CANDIDATES

- A.6 Eligibility of candidates to sit the Diploma examination will be decided by the Board of Examiners.
- A.7 Candidates must possess a medical qualification recognised by the General Medical Council (GMC) in the UK and be included on an appropriate medical register.
- A.8 A Diploma candidate must have completed, by the time of the Diploma Examination, at least two years in a post that provides practical experience and training in pharmaceutical medicine. A senior line manager at the company at which this experience was gained, who, ideally, is also a Member or Fellow of the Faculty and / or the Educational Supervisor, is required to verify on the application form that the candidate has met this requirement.
- A.9 The practical experience in pharmaceutical medicine may be obtained by working in a pharmaceutical company, contract research organisation or drug regulatory authority or, exceptionally, in an academic department. An equivalent amount of part-time training is accepted, provided the candidate has worked at least 2½ days / week in a relevant position.

DIPLOMA REGISTRATION

- A.10 Candidates must complete the application form and submit it with a recent photograph for identity, along with supporting documents, to the Faculty office by the announced closing date.

- A.11 When attending the examination, candidates are required to provide photographic identity (passport, driving licence or ID from place of work) at registration on both days.
- A.12 When submitting the application form, candidates must provide evidence of registration as a medical practitioner by provision of their GMC registration number. Candidates not registered in the United Kingdom should provide the original or a notarised (legally validated) copy and translation of their medical registration certificate. If this does not show current registration then a certificate of good standing will also need to be produced.

EDUCATIONAL SUPERVISOR

- A.13 Candidates who are enrolled with the Faculty and Joint Royal Colleges of Physicians Training Board (JRCPTB) for Pharmaceutical Medicine Specialty Training must have an Educational Supervisor to assist in planning their training in pharmaceutical medicine. In addition, a Senior Specialty Adviser will be allocated to these candidates. It is recommended that candidates who are not enrolling for Pharmaceutical Medicine Specialty Training also have an Educational Supervisor.

SYLLABUS

- A.14 The *Syllabus for Pharmaceutical Medicine* is presented in detail on the Faculty's website and is enclosed in the examination pack.
- A.15 A Diploma candidate should expect questions during the examination on any section of the syllabus. The discipline of pharmaceutical medicine is ever evolving and a Diploma candidate should be aware of important recent changes and current issues.

EXAMINATION

- A.16 The examination is held over two days. The places and times are available from the Faculty about 10 months before the examination and are advertised about 3 months before the closing date for registration.
- A.17 The examination comprises four separate written papers as follows:

Day 1

Multiple Choice Question (MCQ) paper. All 250 questions (50 stems each with 5 choices) should be answered in 1 hour 30 minutes

Short Answer Question paper. All ten questions should be answered in 2 hours 30 minutes

Day 2

Essay paper with a choice of four questions of which two should be answered in 1 hour 30 minutes

Critical Appraisal paper. Candidates will be given 45 minutes to study the set published paper and 1 hour 15 minutes to answer questions on it.

- A.18 Candidates must attend and attempt all four sections of the examination.
- A.19 The final selection of questions for the examination papers is made by the Officers and Panel Convenors of the Board of Examiners. The Board ensures that the examination as a whole covers the syllabus appropriately. Core features of the *short answers* and *critical appraisal* and guidance notes for the markers of the *essays* are checked and agreed.
- A.20 Candidates will be given a time of arrival and finishing on each examination day. These might be earlier than the start of the first written paper and/or later than the finish of the second paper. Candidates will be supervised under examination conditions until the finishing time on each day. Any candidate that arrives late will not be admitted to the examination.
- A.21 Candidates will not be allowed to leave the room within the first 15 minutes of any written paper and candidates arriving late will not be admitted after this time. Any candidate wishing to leave and return to the examination hall will be accompanied.
- A.22 Mobile phones, calculators and other electronic devices may not be used during the examination and, if brought into the examination hall, must be switched off and placed to the side of the room out of sight of all candidates.

ASSESSMENT

- A.23 The multiple-choice questions are marked by computer and grades are then assigned according to pre-set standards. Anomaly monitoring software may be used to detect copying or collusion.
- A.24 Each question in the *Short Answer*, *Essay* and *Critical Appraisal* papers is marked independently by at least two examiners. Individual questions will be marked by the same examiners acting independently for all candidates unless the number of candidates or other factors make this unfeasible. A moderating procedure exists for any individual questions for which a discrepancy arises in the marks awarded.
- A.25 For each section of the examination, one of the following possible grades are awarded: 'Excellent', 'Good', 'Pass', 'Bare Pass', 'Bare Fail',

and 'Fail'. The Board of Examiners approves the correspondence between marks and grades.

ADJUDICATION

- A.26 Before the meeting of the full Board, the Officers and Panel Convenors examine any inconsistencies in a candidate's marks on individual questions and grades and re-assess the relevant papers identified through this process.
- A.27 The Board of Examiners holds its annual meeting approximately six weeks after the examination. The adjudication of the Diploma Examination is a major item, followed by a detailed review of the overall results and of the examination procedures.
- A.28 Candidates are identified by their candidate numbers only throughout the examination until after the adjudication.
- A.29 Each candidate's grades in all four sections are listed and each is considered in turn and a decision reached.
- A.30 An outright 'Fail' in any part of the examination will lead to an overall fail of the examination.
- A.31 Candidates given one 'Bare Fail' may pass the examination if the grades in the other three sections are 'Pass' or higher. A 'Bare Pass' indicates precisely that and candidates with one or more 'Bare Fail' and one or more 'Bare Pass' grades will not pass the examination. Similarly, a candidate with two 'Bare Fails' will fail the examination. During the adjudication process, care is taken by the examiners to review papers with critical borderline grades with re-marking and possible re-grading if considered appropriate.
- A.32 The Board of Examiners may award the Diploma with Distinction to a candidate who has consistently high grades (generally 'Good' or 'Excellent') in all four sections of the examination.

COMMUNICATION OF RESULTS

- A.33 The Faculty will advise all candidates of the outcome in writing.
- A.34 A Diploma certificate will be provided as appropriate.
- A.35 Candidates are not entitled to the return of their answer papers after the examination. Written papers will only be re-marked after the adjudication at the request of the Appeals Panel in response to a well-founded appeal. The Chair cannot enter into detailed discussion with a candidate but will try to be as constructive as possible in any correspondence.
- A.36 An unsuccessful candidate may re-sit the Diploma Examination.

MEMBERSHIP OF THE FACULTY

- A.37 A pharmaceutical physician who has been awarded the Diploma in Pharmaceutical Medicine, meets other eligibility criteria and wishes to become a Member of the Faculty must complete an application form and submit it to the Faculty office.

FEES

- A.38 The Faculty will maintain a schedule of fees, which will be included in the Diploma Examination pack with the conditions that apply clearly stated.

CONDUCT

- A.39 The Faculty may refuse to register a person as a Diploma candidate and may withdraw such registration at any time if the candidate's behaviour is prejudicial before or during the examination by not complying with examination regulations or instructions.
- A.40 The Faculty will investigate any suspected dishonesty or misconduct by a candidate in relation to the Diploma Examination and, if appropriate, revoke the Diploma and Membership.
- A.41 Any candidate who wishes account to be taken of exceptional circumstances or conditions present *BEFORE* the start of the examination that may affect his or her performance must refer to the *Policy for Candidates with Special Requirements*, details of which are available on the Faculty website or from the Faculty office. Such circumstances must be notified to the Chair of the Board of Examiners or the Examinations Administrator *BEFORE SITTING the examination; such information passed to the Faculty after sitting the examination cannot be taken into account.* This information will be kept confidential.
- A.42 Any candidate who wishes account to be taken of exceptional conditions or circumstances arising *AFTER THE START* of the examination must make the invigilator / examiners aware of such circumstances *AT THE TIME* of the examination *AND* make representation in writing as described in the Appeals Procedure. Information provided after the day of the examination shall not be taken into account.
- A.43 The Appeals Procedure should also be followed for any representations by candidates on the conduct of the Diploma Examination. Details are available on the Faculty website or from the Faculty office.

The Faculty of Pharmaceutical Medicine is committed to promoting equal opportunity and eliminating discrimination in all areas of its activity